



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

9050 '02  
DEC 16 2002  
Food and Drug Administration  
College Park, MD 20740

NOV 13 2002

Mr. John Morley  
President  
Natural Factors Nutritional Products, Inc.  
1111 80th Street, S.W.  
Suite 100  
Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letters of September 18, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Natural Factors Nutritional Products, Inc. is making the following claims for the following products:

The product **Celery Seed Extract** uses the claims "Promotes Healthy Blood Pressure...." In the preamble to the January 6, 2000 final rule on structure/function claims for dietary supplements (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claim about promoting healthy blood pressure; that is, a claim that does not make clear that the product is only for people with blood pressure that is already within normal limits implies that the product is intended to treat hypertension, which is a disease.

The product **Anti-ACE Peptides™** uses the claim "Anti-ACE Peptides works to help maintain a healthy circulatory system by inhibiting the production of a compound that increases the degree of constriction of blood vessels." Under 21 CFR 101.93(g)(2)(v), a claim that a product belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease is a disease claim. This product is represented as an

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angiotensin converting enzyme (ACE) inhibitor. ACE inhibitors are widely recognized as therapeutic agents used to treat hypertension, heart failure, and other serious diseases. That your product is represented as an ACE-inhibitor, both in its description as “anti-ACE peptides” and the description of its intended use (i.e., “inhibiting the production of a compound that increases the degree of constriction of blood vessels”), implies that it is intended for use to treat diseases for which an ACE inhibitor may be prescribed.

The product **Zymactive™** uses the claims “...for individuals experiencing inflammation” and “Powerful support for Joints...” These claims constitute an implied disease claim because they describe a characteristic sign (joint inflammation) of a disease (i.e., arthritis or other joint disorder). This is a disease claim under 21 CFR 101.93(g)(2)(ii).

The product **Lung, Bronchial & Sinus Health** uses the claims “...expectorant to help soothe the respiratory airways, thin mucus, and loosen phlegm and bronchial secretions” and “Clears and Soothes the Respiratory Tract.” Taken together, these claims are an implied disease claim because they represent the product to treat sinus and/or bronchial pain or discomfort (i.e., soothe) and abnormal secretion or inability to expel mucous (i.e., clears). These claims are disease claims under 21 CFR 101.93(g)(2)(ii) because they imply that the product is intended to treat characteristic signs or symptoms of bronchial and/or sinus diseases.

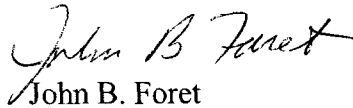
The product **Echinamide™ Anti-V Formula** uses the claims “support the body’s resistance to pathogens” and “supports resistance to pathogens.” Under 21 CFR 101.93(g)(2)(viii), a claim that a product has a role in the body’s response to a disease or a vector of a disease is a disease claim. The claims for your product represent that this product is intended to treat or prevent specific diseases, that is, diseases caused by pathogenic microorganisms.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Page 3 - Mr. John Morley

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, reading "John B. Foret".

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

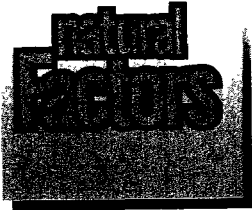
and Applied Nutrition

Copies:

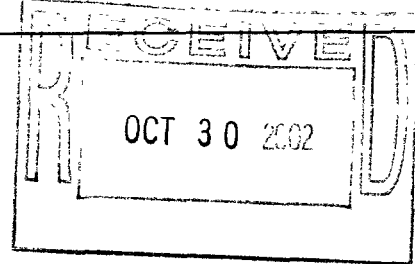
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



# Natural Factors Nutritional Products Inc.



October 10, 2002

Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Echinamide™ Anti-V Formula

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.  
3655 Bonneville Place  
Burnaby, B.C.  
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.  
1111 80<sup>th</sup> Street SW, Suite 100  
Everett, WA 98203

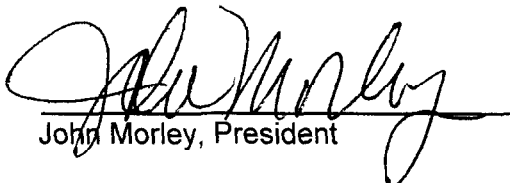
Text of Side Panel: Anti-V Formula is the optimal formula to support the body's resistance to pathogens.

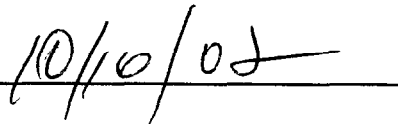
Text on PDP: Supports Resistance To Pathogens

Name of dietary ingredient that is the subject of statement: Echinamide™, Lomatium, Astragalus, Reishi mushroom, Licorice

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

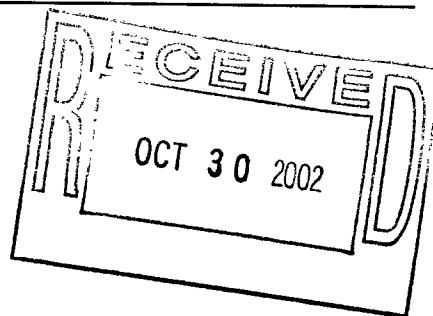
  
John Morley, President

  
Date



# Natural Factors Nutritional Products Inc.

September 18, 2002



Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

Dear Sir or Madam:

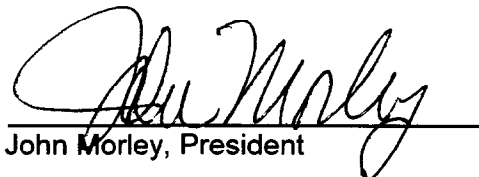
This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

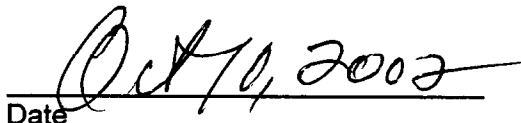
Supplement:	Lung, Bronchial & Sinus Health
Manufacturer, packer:	Natural Factors Nutritional Products, Ltd. 3655 Bonneville Place Burnaby, B.C. Canada V3N 4S9
Distributor:	Natural Factors Nutritional Products, Inc. 1111 80 <sup>th</sup> Street SW, Suite 100 Everett, WA 98203
Text of Side Panel:	Dr. Murray's respiratory formula is an all-natural expectorant to help soothe the respiratory airways, thin mucus, and loosen phlegm and bronchial secretions.
Text on PDP:	Clears and Soothes the Respiratory Tract

Name of dietary ingredient that is the subject of statement: Glycerol Guaiacolate, N-Acetyl-L-Cysteine, Bromelain, Marshmallow (*Althaea officinalis*), powdered extract 4:1 (root), Mullein (*Verbascum thapsus*), powdered extract 4:1 (leaf), Wild Cherry (*Prunus serotina*), powdered extract 4:1 (bark), Horehound (*Marrubium vulgare*), powdered extract 4:1 (aerial part), Ivy (*Hedera helix* L), powdered extract 7.5:1 (aerial part).

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

  
John Morley, President

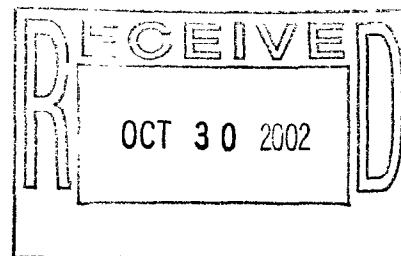
  
Date

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# Natural Factors Nutritional Products Inc.

September 19, 2002



Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Zymactive™

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.  
3655 Bonneville Place  
Burnaby, B.C.  
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.  
1111 80<sup>th</sup> Street SW, Suite 100  
Everett, WA 98203

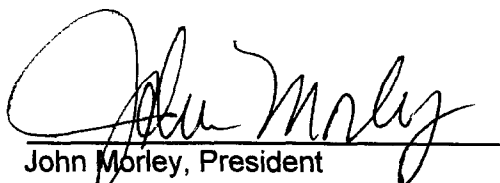
Text of Side Panel: Zymactive™ provides a spectrum of protein-digesting enzymes useful in supporting proper digestive function as well as nutritional support for individuals experiencing inflammation.

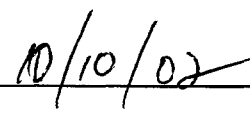
Text on PDP: Powerful Support For Joints & Good Health

Name of dietary ingredient that is the subject of statement: Calcium (from calcium carbonate), Magnesium (from magnesium citrate), Pancreatin 8X, Papain 30,000 UPS/mg, Peptizyme SP® 200,000 SPU/g, Bromelain 1,200 MCU/g.

Name of the dietary supplement: Natural Factors

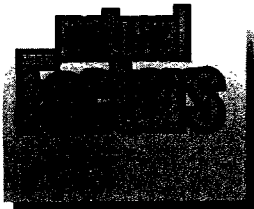
I represent the information presented to be accurate and in compliance with supplement label regulations.

  
John Morley, President

  
Date

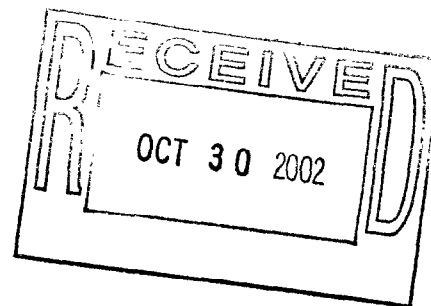
1111 80th Street S.W., Suite 100  
Everett, WA 98203  
Phone: (425) 513-8800  
Fax: (425) 348-9050

82385



# Natural Factors Nutritional Products Inc.

September 18, 2002



Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Celery Seed Extract

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.  
3655 Bonneville Place  
Burnaby, B.C.  
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.  
1111 80<sup>th</sup> Street SW, Suite 100  
Everett, WA 98203

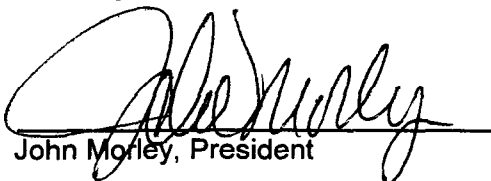
Text of Side Panel: Celery Seed Extract contains 85% 3-n-butylphthalide, or 3nB for short - a beneficial compound unique to celery. One capsule provides the same level of 3nB as 4-6 ribs of celery

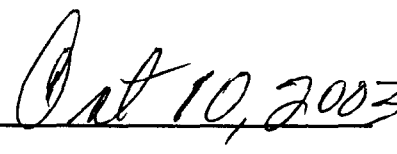
Text on PDP: Promotes Healthy Blood Pressure, Joint Health & Normal Uric Acid Levels

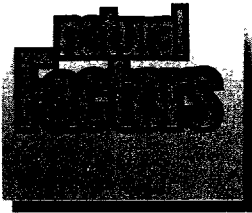
Name of dietary ingredient that is the subject of statement: Celery (*Apium graveolens*) seed extract

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

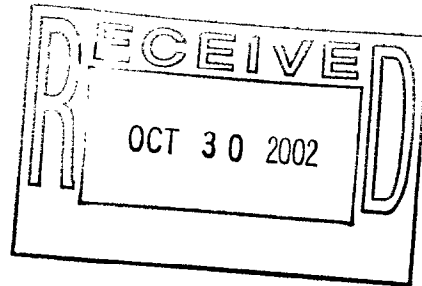
  
John Morley, President

  
Date



# Natural Factors Nutritional Products Inc.

September 18, 2002



Food and Drug Administration  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Anti-ACE Peptides™

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.  
3655 Bonneville Place  
Burnaby, B.C.  
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.  
1111 80<sup>th</sup> Street SW, Suite 100  
Everett, WA 98203

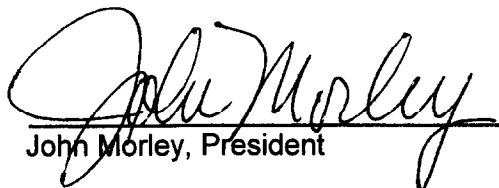
Text of Side Panel: Anti-ACE Peptides™ works to help maintain a healthy circulatory system by inhibiting the production of a compound that increases the degree of constriction of blood vessels.

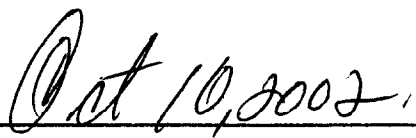
Text on PDP: Supports a Healthy Circulatory System

Name of dietary ingredient that is the subject of statement: Anti Angiotensin Converting Enzyme (ACE) Peptides

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.

  
John Morley, President

  
Date